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Office of Chemical Safety and Pollution Prevention

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MEMORANDUM

SUBJECT: Reduced Risk Assessment for Chlorantraniliprole Use on Peanut

TO: Stephen Schaible

Reduced Risk Committee Chair

Registration Division

Office of Pesticide Programs (7505P)

James Cowles
Associate Director

Environmental Fate and Effects Division

Office of Pesticide Programs (7507P)

FROM: Michael B. Lowit, Ph.D., Ecologist

Christopher M. Koper, Chemist

Edward Odenkirchen, Ph.D., Senior Science Advisor

Sujatha Sankula, Ph.D., Acting Branch Chief A.

Environmental Risk Branch I

Environmental Fate and Effects Division (7507P)

Office of Pesticide Programs

DuPont submitted a proposal for reduced risk status on chlorantraniliprole use on peanut. Reduced risk status for chlorantraniliprole use on peanut was previously requested but in comparison to different alternative products. The registrant claim of reduced risk is primarily based on human health effects rather than environmental benefits. This memorandum summarizes the review of the current reduced risk claim. EFED also received a request to conduct a risk assessment for the proposed use of chlorantraniliprole on peanut (DP 412479). Peanut use at a lower application rate was previously assessed (DP 361404) but registration was not granted based on the Human Effects Division (HED) risk assessment which indicated that "peanut field trials must be conducted at six locations in the US that represent major peanut growing regions if the petitioner plans to add peanut to the label. Translation from radish root is not possible." (communication with Jennifer Urbanski, Registration Division, 6/5/2013).

This review is based on the merits of the submitted package only. The registrant identified alternative pesticides and provided a comparison of chlorantraniliprole's fate properties and toxicity values to those of the alternatives. The alternative pesticides are acephate, beta-cyfluthrin, diflubenzuron, esfenvalerate, flubendiamide, indoxacarb, and *lambda*-cyhalothrin.

No comparative toxicity data were provided for plants (aquatic or terrestrial), chronic exposure to marine/estuarine fish and invertebrates, or chronic exposure to mammals (i.e., 2-generation reproduction study). Although not submitted with the package, chlorantraniliprole data are available for these assessment endpoints. Given the potential for persistence of chlorantraniliprole in the environment, a comparison of the compound to alternative pesticides on a chronic basis should be considered essential.

Peanut use is proposed as a foliar (aerial or ground) application up to 0.067 lb ai/A (three applications; three day interval) at a maximum rate of 0.2 lb ai/A per year. The proposed application rate is slightly higher than the previously assessed peanut use rate and similar to numerous other uses with foliar application. It is noted that previous Section 3 risk assessments for chlorantraniliprole use, including use on peanut (e.g., D338512, D361404, D377697, D381819, D397575, and D404738), identified direct risk concerns for freshwater and estuarine/marine invertebrates. Those assessments also identified potential risk to terrestrial invertebrates. Direct risk concerns have also been identified for birds but only for chlorantraniliprole-treated seed use (e.g., D377697 and D381819).

Reduced risk status for chlorantraniliprole use on peanut was previously assessed in 2010. The previous request was based on comparison to a different set of alternative pesticides; four of the seven alternative pesticides identified in the current request were not considered previously. Nonetheless, conclusions from the previous request are similar to those reached for this request. All reduced risk requests for chlorantraniliprole to date have been approved.

Fate Concerns

Fate concerns for chlorantraniliprole include persistence and mobility. Environmental fate data indicate that chlorantraniliprole is persistent in terrestrial and aquatic environments. Extended chlorantraniliprole use is expected to cause accumulation of residues in soil from year to year and may contribute to groundwater contamination. Major routes of dissipation include photodegradation in water, leaching, and runoff. Aerobic aquatic metabolism (DT₅₀) half-lives range from 125-231 days. Aerobic soil metabolism (DT₅₀) half-lives range from 233-886 days. The compound is stable to hydrolysis at pH 7; however, its photolysis value in water is less than 1 day (0.37 days). It is important to note that this value is calculated from an experiment using continuous irradiation using a xenon arc lamp (MRID 46889018). Using this value may underestimate the aqueous photolysis half-life by up to two orders of magnitude since an additional study submitted by the registrant (MRID 46889112), calculates a photolysis half-life of 32.8 days for chlorantraniliprole exposed to natural sunlight, which is considered to be more appropriate to characterize aqueous photolysis of

chlorantraniliprole in the environment. Chlorantraniliprole is moderately mobile in soils and sediment (Koc = 180-539). In terrestrial field studies, chlorantraniliprole dissipated with half-lives ranging from 123-1130 days. Bioaccumulation data indicate that chlorantraniliprole is not likely to bioaccumulate with a BCF ranging from 13-15 in whole fish.

Chlorantraniliprole has greater half-lives (i.e., is more persistent) for 6 out of 7 compared alternative pesticides for the aerobic aquatic metabolism and aerobic soil metabolism studies and has the longest terrestrial field dissipation half lives among all compared alternatives. In addition, it is more mobile than six of the seven alternative pesticides. It is stable to hydrolysis which is similar to compared alternatives. Keeping in mind the differences between natural and artificial aqueous half-life calculations mentioned above, the aqueous photolysis half-life using artificial light is shortest among all compared alternative pesticides. Concerning bioconcentration, chlorantraniliprole has the lowest BCF factor and log Kow values for six of the seven alternative pesticides.

Summary of chlorantraniliprole toxicity compared to alternative insecticides

In general terms, chlorantraniliprole appears to be less acutely toxic than some of the alternatives to birds, mammals, terrestrial insects, and fish while it appears to be more or less toxic (depending on the alternative) to birds on a chronic basis and aquatic invertebrates on an acute and chronic basis (a comparison is provided in **Appendix A**). In some cases a comparison cannot be made to an alternative product because toxicity has not been established (i.e., toxicity was not reported or a study yielded a non-definitive value).

More specifically, chlorantraniliprole is less toxic than many of the alternative pesticides to mammals (acute) and terrestrial invertebrates (acute); comparison cannot be made for two of the alternatives because of lack of data and non-definitive endpoints. Chlorantraniliprole is shown to be less toxic to birds for only a few of the alternative products (most clearly acephate on an acute and chronic basis) while it is more toxic than some of the alternatives on a chronic basis. Further comparison of bird data cannot be made due to a lack of data (mostly chronic) and non-definitive endpoints (mostly acute). Chlorantraniliprole is less acutely toxic to fish (freshwater and marine/estuarine) than most of the alternative products (non-definitive endpoints and uncertainty due to comparison of different species account for the other alternative products); however, it is clearly less toxic on a chronic basis than only one of the alternative products. Comparative toxicity to aquatic invertebrates is less clear; although chlorantraniliprole is less acutely toxic than most of the alternative pesticides to mysid (acute), it is more toxic than some of the alternative pesticides to oysters (acute) and daphnia (acute and chronic).

Conclusions

EFED reiterates that the assessment of this reduced risk request review is based solely on a review of the registrant-submitted fate and effects data. Ultimately it is the relationship between toxicity and exposure which will determine actual risk.

Although chlorantraniliprole is less bioaccumulative than all compared alternative pesticides, its persistence in aquatic and terrestrial environments and mobility in soils and sediment are of concern; therefore, reduced-risk status should not be granted solely on the basis of its fate properties.

Based on the available toxicity data, it appears that use of chlorantraniliprole on peanut may be a reasonable candidate for a reduced risk submission as it is less toxic than some of the alternative pesticides, depending on the taxonomic group. Comparative toxicity data were not provided for plants (aquatic or terrestrial), chronic exposure to marine/estuarine fish and invertebrates, or chronic exposure to mammals (i.e., 2-generation reproduction study) but chlorantraniliprole toxicity data are available for these assessment endpoints. Previous risk assessments could not preclude risk to dicots (seedling emergence); however, lack of comparative plant data is unlikely to factor into the reduced risk decision given that chlorantraniliprole is an insecticide and its mode of action (binding with insect ryanodine receptors). Previous assessments have identified chronic risk concerns for direct effects on marine/estuarine invertebrates from some uses (not peanut, as previously assessed). Direct chronic risk concerns have not been identified for estuarine/marine fish or mammals.

In summary, compared to some of the alternatives, chlorantraniliprole has a relatively favorable toxicity profile for the taxonomic groups that data were provided but there is concern about its persistence and mobility. Overall, the submitted information supports a claim for reduced risk for chlorantraniliprole use on peanut.

Appendix A

Comparative toxicity of chlorantraniliprole and alternative pesticides provided by the registrant

Alternative pesticides that were considered: acephate, beta-cyfluthrin, diflubenzuron, esfenvalerate, flubendiamide, indoxacarb, and *lambda*-cyhalothrin.

1. Terrestrial Toxicity

a. Animals

i. Acute Toxicity

Birds

Chlorantraniliprole is less toxic to quail than three (indoxacarb and acephate on an oral and dietary-basis; esfenvalerate on an oral-basis only) of the seven alternative products. Chlorantraniliprole is less toxic to duck than esfenvalerate. Quail data were not available for *lambda*-cyhalothrin (oral-basis) or diflubenzuron (dietary-basis).

Mammals

Chlorantraniliprole is less toxic than five (acephate, beta-cyfluthrin, esfenvalerate, indoxacarb, and *lambda*-cyhalothrin) of the seven alternative products. Data were not available for diflubenzuron.

Invertebrates

Chlorantraniliprole is less toxic than five (acephate, beta-cyfluthrin, esfenvalerate, indoxacarb, and *lambda*-cyhalothrin) of the seven alternative products.

ii. Chronic Toxicity

Birds

Chlorantraniliprole is less toxic than three of the seven alternative products to at least one brid species (acephate – quail and duck, beta-cyfluthrin – duck, and flubendiamide - duck). Chlorantraniliprole is at least an order of magnitude more toxic to quail than beta-cyfluthrin and flubendiamide. No data were available for diflubenzuron or esfenvalerate. Quail data were not available for *lambda*-cyhalothrin.

Mammals

No data were provided.

b. Plants

No data were provided.

2. Aquatic Toxicity

a. Animals

i. Acute Toxicity

Freshwater Fish

Chlorantraniliprole is less toxic than six (acephate, beta-cyfluthrin, diflubenzuron, esfenvalerate, indoxacarb, and *lambda*-cyhalothrin) of the seven alternative products to at least one fish species (bluegill sunfish or rainbow trout).

Freshwater Invertebrates

Chlorantraniliprole is less toxic than four (beta-cyfluthrin, diflubenzuron, esfenvalerate, and *lambda*-cyhalothrin) of the seven alternative products. However, it is more toxic than three alternative products (acephate, flubendiamide, and indoxacarb).

Marine/Estuarine Fish

Chlorantraniliprole is less toxic than four (acephate, beta-cyfluthrin, esfenvalerate, and *lambda*-cyhalothrin) of the seven alternative products.

Marine/Estuarine Invertebrates

Chlorantraniliprole is less toxic to mysid than six (acephate, beta-cyfluthrin, diflubenzuron, esfenvalerate, indoxacarb, and *lambda*-cyhalothrin) of the seven alternative products. It is less toxic to oyster than two (beta-cyfluthrin and *lambda*-cyhalothrin) of the alternative products; however, it is more toxic than three of the alternatives (acephate, flubendiamide, and indoxacarb). Oyster data were not provided for diflubenzuron or esfenvalerate.

ii. Chronic Toxicity

Freshwater Fish

Chlorantraniliprole is less toxic than beta-cyfluthrin. It may also be less toxic than *lambda*-cyhalothrin; however, there is uncertainty because data on the same species was not provided for both chemicals. Data were not provided for three of the alternative products (acephate, diflubenzuron, and esfenvalerate).

Freshwater Invertebrates

Chlorantraniliprole is less toxic than four (acephate, diflubenzuron, esfenvalerate, and *lambda*-cyhalothrin) of the seven alternative products and more toxic than two (flubendiamide and indoxacarb). Data were not provided for beta-cyfluthrin.

Marine/Estuarine Fish

No data were provided.

Marine/Estuarine Invertebrates

No data were provided.

b. Plants

No data were provided.